REMARKS

The final Office Action of July 9, 2008, and the Advisory Action of November 17, 2008, have been received and reviewed.

Claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, and 59-78 are currently pending and under consideration in the above-referenced application. Each of claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, and 59-78 has been rejected.

Claims 1, 16, 50, and 68 have been amended and new claims 79 and 80 have been added.

Reconsideration of the above-referenced application is respectfully requested.

Claim Objection

Claim 16 was objected under 37 C.F.R. § 1.75(c) for being of improper dependent form for failing to further limit the subject matter of a previous claim. Specifically, claim 16 depends from a claim (claim 13) that has been canceled.

Claim 16 has been amended to depend from independent claim 1. It is respectfully submitted that claim 16 further defines the nutritional supplement recited by independent claim 1. Accordingly, withdrawal of the objection to claim 16 is respectfully solicited.

Rejections under 35 U.S.C. § 112, First Paragraph

Claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, and 59-78 have been rejected uner the first paragraph of 35 U.S.C. § 112 for reciting compositions that "consist essentially of" the listed ingredients.

The Office has not provided any support for its assertion that the as-filed specification must specifically identify the essential components of a composition when the transitional phrase "consisting essentially of" is used. Nonetheless, it is respectfully submitted that the specification of the as-filed specification of the above-referenced application provides examples of compositions that include a limited number of essential ingredients, including those recited by independent claims 1, 50, and 68.

In any event, each of these claims has been amended to recite a nutritional supplement that includes a cardiovascular support component that "consists of" the listed components.

Again, the as-filed specification provides support for the recitations of amended independent claims 1, 50, and 68. *See, e.g.,* paragraph **[0017]** (independent claim 1); paragraph **[0031]** (independent claim 68).

Withdrawal of the 35 U.S.C. § 112, first paragraph, rejections of independent claims 1, 50, and 68, and of their dependent claims 4-8, 11, 12, 14-16, and 18, 50, 53-57, and 59-67, and 69-78 be withdrawn.

Rejections under 35 U.S.C. § 103(a)

Claims 1, 4-8, 11, 12, 14-16, 50, 53-57, and 59-78 have also been rejected under 35 U.S.C. § 103(a).

There are several requirements in establishing a *prima facie* case of obviousness against the claims of a patent application. All of the limitations of the claim must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974); *see also* MPEP § 2143.03. Even then, a claim "is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007). The Office must also establish that one of ordinary skill in the art would have had a reasonable expectation of success that the purported modification or combination of reference teachings would have been successful. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). There must also be "an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR* at 1396. That reason must be found in the prior art, common knowledge, or derived from the nature of the problem itself, and not based on the Applicant's disclosure. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006). A mere conclusory statement that one of ordinary skill in the art would have been motivated to combine or modify reference teachings will not suffice. *KSR* at 1396.

Ramaekers in View of Rath, Tentolouris, Cholesterol-Lowering Drugs, Focant, or Kirkpatrick

Claims 1, 7, 8, 11, 12, 14, 15, 50, 56, 57, 59-64, 67, and 72-78 stand rejected under 35 U.S.C. § 103(a) for reciting subject matter which is assertedly unpatentable over the

subject matter taught in U.S. Patent 6,506,413 to Ramaekers (hereinafter "Ramaekers"), in view of teachings from U.S. Patent 5,650,418 to Rath et al. (hereinafter "Rath"); Tentolouris et al., *"L-Arginine in coronary atherosclerosis,"* International Journal of Cardiology, 75 (2000), pp. 123-128 (hereinafter "Tentolouris"); "Cholesterol-Lowering Drugs" (http://www.americanheart.org/presenter.jhtml?identifier=4510) (3 pages) (hereinafter "Cholesterol-Lowering Drugs"); Focant et al., "The Effect of Vitamin E Supplementation of Cow Diets Containing Rapeseed and Linseed on the Prevention of Milk Fat Oxidation," Journal of Dairy Science, 81 (1998) pp. 1095-1101 (Abstract) (hereinafter "Focant"); Gordon, *"Cardiovascular Research,"* Explore (1999) (hereinafter "Gordon"), http://www.explorepub.com/articles/heart_disease.html (11 pages) (hereinafter "Gordon"); or Kirkpatrick, *"Properties and Activities of Transfer Factor,"* Journal of Allergy and Clinical Immunology, 55(6) (1975), pp. 411-421 (Abstract) (hereinafter "Kirkpatrick").

The teachings of Ramaekers are directed to compositions for treating various ailments in animals. Each of the disclosed compositions includes either transfer factor and a lactic acid-forming bacteria or transfer factor, zinc, and an essential fatty acid. Ramaekers does not teach or suggest that any of the disclosed compositions is useful for treating a cardiovascular disorder.

Rath teaches compositions that are useful for treating cardiovascular disorders. The essential components of such compositions are ascorbate, nicotinic acid, and lysine, which are "preferentially present in a ration of 8:1:1."

The teachings of Tentolouris relate to the benefits of L-arginine. Specifically, Tentolouris teaches that nitric oxide, which is formed as the N-guadino terminal end of L-arginine, is useful in improving blood flow through coronary arteries.

Cholesterol-Lowering Drugs discusses various drugs that are useful in lowering blood cholesterol levels, particularly in patients who are at risk for coronary heart disease.

Focant teaches that oxidation of the milk of cows that eat rapeseed and linseed may reduced by supplementation with vitamin E. The teachings of Focant have nothing to do with compositions for treating cardiovascular disorders.

The teachings of Gordon relate to compositions that apparently include non-specific transfer factor in combination with a large number of other components, including components that lower circulating immune complexes, components that lower fibrinogen levels, components that lower elevated C-reactive proteins, and (heavy metal) detoxification/chelation components.

Kirkpatrick teaches that transfer factor has "direct effects on inflammatory sites."

It is respectfully submitted that the teachings of Ramaekers, in combination with any of Rath, Tentolouris, Cholesterol-Lowering Drugs, Focant, Gordon, or Kirkpatrick do not support a *prima facie* case of obviousness against any of claims 1, 7, 8, 11, 12, 14, 17, 50, 56-64, 66, or 72-78 for at least two reasons.

First, none of the references that have been relied upon in rejecting claims 1, 7, 8, 11, 12, 14, 17, 50, 56-64, and 66 teaches or suggests a composition that includes transfer factor that is specific for at least one of herpes simplex virus type I, herpes simplex virus type II, cytomegalovirus, *Chlamydia pneumoniae,* and *Heliobacter pylori,* as is required of the compositions recited in amended independent claims 1 and 50. In this regard, although Ramaekers notes that mammalian transfer factor was previously used to treat HSV infections (col. 1, lines 21-22) without disclosing whether or not the transfer factor so used was actually specific for HSV, the teachings and suggestions of Raemaekers are limited to compositions that include transfer factor to treat *animal pathogens*. The teachings of Kirkpatrick are limited to a broad discussion of transfer factor without any teaching or suggestion regarding specificity, and the teachings of Gordon are limited to transfer factor that "may improve resistance to Herpes, CMV, Chlamydia, and Helicobacter [sic]" without teaching or suggesting that the transfer factor of the disclosed composition may be specific for any of these pathogens.

Second, with respect to the subject matter recited in independent claims 1, 50, and 68 and their respective dependent claims, it is respectfully submitted that there would have been no apparent reason for one of ordinary skill in the art to combine teachings from Ramaekers with teachings from any of Rath, Tentolouris, Cholesterol-Lowering Drugs, Focant, Gordon, or Kirkpatrick in the manner that has been asserted. This is because each of independent claims 1, 50, and 68, as amended, recites a nutritional supplement that consists of a variety of components, including a cardiovascular support component. The cardiovascular support

component of each of independent claims 1, 50, and 68 consists of transfer factor and other listed elements. None of the elements listed in amended independent claims 1, 50, or 68 includes a lactic acid-forming bacteria or zinc and an essential fatty acid, as are present in each of the compositions disclosed by Ramaekers. Additionally, Rath, Cholesterol-Lowering Drugs, and Gordon teach compositions that include a number of additional essential elements that are not recited in amended independent claim 1, amended independent claim 50, or amended independent claim 68.

As for the subject matter to which independent claim 72 and its dependent claims 73-78 are drawn, none of Ramaekers, Rath, Tentolouris, Cholesterol-Lowering Drugs, Focant, Gordon, or Kirkpatrick, taken alone or in any combination, teaches or suggests a composition that includes a preparation including transfer factor and vitamin C in the same amounts.

The Office has not provided any reasoning to support its rejection of independent claim 72 or its dependent claims 73-78, let alone an apparent reason for one of ordinary skill in the art would to have been motivated to modify teachings from Ramaekers or to combine teachings from Ramaekers with teachings from any of the other cited references to develop a composition that includes transfer factor and vitamin C in the same amounts.

Therefore, it is respectfully submitted that the Office has not established a *prima facie* case of obviousness against any of claims 1, 7, 8, 11, 12, 14, 15, 50, 56, 57, 59-64, 67, or 72-78, as would be required to maintain the 35 U.S.C. § 103(a) rejections of these claims.

Ramaekers, Tentolouris, and Tokoro

Claims 4-6, 53-55, 68, 70, and 71 stand rejected under 35 U.S.C. § 103(a) for being directed to subject matter that is allegedly unpatentable over the teachings of Ramaekers, in view of teachings from Tentolouris and, further, in view of the subject matter taught in U.S. Patent 5,080,895 to Tokoro (hereinafter "Tokoro").

It is respectfully submitted that claims 4-6 are allowable, among other reasons, for depending directly or indirectly from independent claim 1, which is allowable.

Each of claims 53-55 is allowable, among other reasons, for depending directly or indirectly from independent claim 50, which is allowable.

Furthermore, the teachings of Ramaekers, Tentolouris, and Tokoro do not support a *prima facie* case of obviousness against any of claims 4-6, 53-55, 68, 70, or 71.

In this regard, it is respectfully submitted that, as the compositions disclosed in Ramaekers include essential components (*e.g.,* lactic acid-forming bacteria or zinc and an essential fatty acid) in addition to those of the compositions to which claims 4-6, 53-55, 68, 70, and 71 are directed, there would have been no motivation for one of ordinary skill in the art to modify the teachings of Ramaekers or to combine them with teachings from Tentolouris and Tokoro to develop the compositions that are recited in these claims.

It is further submitted that none of Ramaekers, Tentolouris, or Tokoro teaches or suggests a composition that includes non-mammalian transfer factor. Although Tokoro has been relied upon in this respect, Tokoro does not actually include any teaching or suggestion that transfer factor may be obtained from chickens eggs. Rather, the teachings of Tokoro are limited to a "transfer factor-like" substance, which is known in the art to be different from transfer factor. *See, e.g.,* Dunnick, W., et al., "Lack of Antigen Fragments in Guinea Pig Transfer Factor-like Activity, Clin. Immunol. and Immunopathol. 17: 55-65 (1980), at page 65. A "transfer factor-like" substance, such as the "unknown food factor" described in U.S. Patent 4,402,938 to Collins et al. (*see, e.g.,* Tokoro, col. 7, lines 51-53) or nucleosides, which have molecular weights of less than about 2,000 Da, may cause a non-specific improvement in treated animal's immune system response. While that improvement could be viewed superficially as similar to the way that immune system would respond to transfer factor, it is generally accepted by those of ordinary skill in the art that these "transfer factor-like" substances are incapable of causing the immune system of a treated animal to elicit a specific response (*i.e.,* a response to a particular antigen). Transfer factor, in contrast, is known to those of ordinary skill in the art to elicit a specific response from the immune system of a treated animal. In any event, Tokoro clearly indicates to those of ordinary skill in the art that the "transfer factor-like" substance described therein is not transfer factor. Specifically, Tokoro provides that "the immunological functions of the transfer factor-like component . . . are not known" (col. 7, lines 44-47), whereas the literature indicates that the immunological functions of transfer factor were very well known before the earliest date to which a claim for priority has been made in Tokoro.

It is also well known in the art that transfer factor-like substances are incapable of causing the immune system of a treated animal to elicit a specific response (*i.e.,* a response to a particular antigen), while transfer factor can elicit a specific response from the immune system of a treated animal.

Therefore, it is respectfully submitted that each of claims 4-6, 53-55, 68, 70, and 71 is directed to subject matter that is allowable over the subject matter taught by Ramaekers, Tentolouris, and Tokoro.

Ramaekers in View of Singh

Claims 1, 16, 50, 62, and 65 stand rejected under 35 U.S.C. § 103(a) for being directed to subject matter that is purportedly unpatentable over the subject matter taught in Ramaekers, in view of teachings from Singh et al., "Coenzyme Q in cardiovascular disease," Assoc. Physicians India. (Mar 1998) 46(3):299-306 (Abstract) (hereinafter "Singh").

Independent claims 1 and 50 are allowable, among other reasons, because the teachings of Ramaekers are limited to compositions that essentially include lactic acid-forming bacteria or zinc and an essential fatty acid, whereas amended independent claims 1 and 50 are drawn to nutritional supplements that consist of various recited elements, including cardiovascular support components, none of which includes a lactic acid-forming bacteria or zinc and an essential fatty acid. Therefore, there would have been no apparent reason for one of ordinary skill in the art to have relied upon teachings from Ramaekers to develop a composition of the type recited by independent claim 1 or of the type recited by independent claim 50.

Claim 16 is allowable, among other reasons, for depending from independent claim 1, which is allowable.

Claims 62 and 65 are both allowable, among other reasons, for depending from independent claim 50, which is allowable.

Ramaekers, Tentolouris, and Pearson

Claims 68 and 69 stand rejected under 35 U.S.C. § 103(a) for reciting subject matter which is assertedly unpatentable over that taught in Ramaekers, in view of teachings from

Tentolouris, in light of the subject matter taught in U.S. Patent 6,693,094 to Pearson et al. (hereinafter "Pearson").

Claim 69 is allowable, among other reasons, for depending from independent claim 68, which is allowable.

For these reasons, withdrawal of the 35 U.S.C. § 103(a) rejections of claims 1, 4-8, 10-12, 14-16, 50, 53-66, and 68-78 is respectfully solicited, as is the allowance of each of these claims.

New Claims

New claims 79 and 80 have been added. Both are independent claims that are drawn to nutritional supplements with specific ingredients. It is respectfully submitted that neither of these claims introduces new matter into the above-referenced application. It is further submitted that both new independent claim 79 and new independent claim 80 are drawn to subject matter that is allowable over the art of record.

CONCLUSION

It is respectfully submitted that each of claims 1, 4-8, 10-12, 14-16, 50, 53-66, and 68-80 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,

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Date: December 9, 2008

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